

REMARKS

I. Status of the Claims

Claims 1-60 are pending in the application. Claims 1-17, 20-23 and 27-60 stand withdrawn, and claims 1-17 and 20-23 have been canceled without prejudice or disclaimer. Claims 18, 19 and 24-26 are rejected as indefinite under 35 U.S.C. §112, second paragraph, claims 24-26 are rejected as lacking written description and enablement under 35 U.S.C. §112, first paragraph, and claims 24-26 are rejected as anticipated under 35 U.S.C. §102. The specific grounds for rejection, and applicants' response thereto, are set out in detail below.

II. Objections

A. Specification

The specification is objected to for numerous informalities which have been addressed by appropriate amendments. Applicants submit that none of the hyperlinks at pages 6 and 7 are executable (applicants note that the action itself states that the absence of an “http:” renders the hyperlinks non-executable and therefore proper). Further, applicants request that the objection to the Abstract be held in abeyance as applicants may be entitled to rejoinder of one or more method claims. Reconsideration and withdrawal of the objections is otherwise requested.

B. Drawings

FIG. 1 is objected to as not accurately depicting gray shaded regions. A replacement figure is provided (see attached). The figure legend for FIG. 2 references “color” bars while the figure itself is not in color. Applicants have amended the legend to refer instead to “pattern” bars, which need not reflect any color. Reconsideration and withdrawal of the objections is requested.

C. Claims

Claims 25 and 26 are objected to as substantial duplicates of each other. Applicants traverse. Reference to the plain language of the claims reveals that claim 25 is directed to particular *overall lengths* of the oligopeptide, whereas claim 26 refers to the number of *consecutive residues* from the referenced sequence. These are distinct embodiments and do not run afoul of the “claim duplication” prohibition of 37 C.F.R. §1.75. Reconsideration and withdrawal of the objection is requested.

III. Rejections Under 35 U.S.C. §112

A. First Paragraph

Claims 24-26 stand rejected as lacking an adequate written description or enabling disclosure. Applicants traverse both rejections as lacking adequate legal and factual foundations.

Written Description. The examiner posits 5 factors for analyzing the written description requirement. Of these, level of skill in the art and method of making clearly mitigate *in favor* of written description, as the skill is admittedly high, and making peptides of a known sequence is trivial. With regard to partial structure, applicants submit that while the number of possible oligopeptides falling within the scope of the claim is large, it is a straightforward matter to identify each of these. Applicants could easily have generated a sequence listing with each and every peptide using a simply computer program. However, since it would immediately be evident to any skilled artisan up a reading of the specification what peptides were envisioned, there would be no reason so submit such a listing. Thus, the very nature of this rejection creates a high burden on the examiner to come forward with *compelling* evidence or scientific rationale

as to why applicants' claim would not readily be recognized by those of skill in the art as part of their invention.

Turning to the remaining factors, functional characteristics and physical/chemical properties, applicants submit that the examiner incorrectly states that "the claims are drawn to a method of increasing the efficiency of an intein-mediated protein splicing/ligation comprising expressing a fusion protein comprising said intein." However, inteins are not mentioned in this application.

The examiner also states that the claims "do not describe biological function of the claimed oligopeptide." That statement is irrelevant, as there is no need for applicants to provide a biological function *in the claims*. The examiner then comments on the large number of possible oligopeptides and how they might vary as compared to SEQ ID NO:3 as a whole. Again, that is not relevant, since applicants do not allege that the oligopeptides will have the function of SEQ ID NO:3. Next, the examiner states that there are no working examples showing biological function of the oligopeptides. While true, this is again not relevant to written description. The question here is not enablement, but whether one of skill in the art would readily recognize that applicants were in "possession" of the invention as claimed.

Finally, the examiner argues that one would not be able "assay or characterize functional peptide in order for the above-mentioned detection and identification [to be achieved]" However, this argument again focuses on enablement requirements – *making and using* – and not on those dealing with written description.

In sum, the examiner, while properly citing factors that should be applied to a written description analysis, then fails to actually *follow* these factors and instead falls back on arguments that can only be viewed as directed to the issue of enablement. Thus, the only

relevant argument provided by the examiner is that the genus of claimed oligopeptides is too large. However, that argument alone, without supporting evidence, will not suffice to establish a *prima facie* rejection for lack of written description under §112, first paragraph. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

Enablement. Here, again the examiner has made proper reference to the factors under consideration when analyzing enablement under §112, first paragraph. And unlike in the preceding rejection, in the application of these factors the examiner has cited to relevant issues, such as the lack of evidence of biological function for the peptides. However, when *all* the factors are examined, as required by the controlling case law, a holding of non-enablement will not stand.

Again, applicants readily admit that the genus of claimed oligopeptides is large. Applicants will also admit that there is no evidence regarding functional relationship between the claimed oligopeptides and SEQ ID NO:3. However, since applicants are not *claiming* such a functional relationship, this fact has no more significance than does the sheer number of species within the claimed genus. And indeed, the examiner has not made any mention of issues surrounding *making* the claimed oligopeptides, so what is left here is the argument that there is no enabled use for the claimed peptides. It is this point alone on which the rejection hangs.

As noted in the application, at page 26, one can use peptides to produce antibodies which can then be used diagnostic applications. While it is true that not every oligopeptide will produce antibodies that cross-react with the native Vac14 sequence, one would expect many (in fact the majority) of such oligopeptides to elicit at least a polyclonal response the would react to some extent with a denatured form of SEQ ID NO:3. This is sufficient to enable the peptides generally, and the possible inclusion of a few inoperative species is not enough to denude the

claims of enablement. The presence of inoperative embodiments within the scope of a claim does not necessarily render a claim nonenabled. See MPEP §2164.08. “The standard is whether a skilled person could determine which embodiments that were conceived, but not yet made, would be inoperative or operative with expenditure of no more effort than is normally required in the art.” Citing *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984). Even a large number of operable embodiments does not always render a claim broader than the enabled scope when undue experimentation is not involved in determining which embodiments are operable. See *In re Angstadt*, 537 F.2d 498, 502-503, 190 USPQ 214, 218 (CCPA 1976).

Here, there can be no question that raising antibodies or antiserum against a given peptide is trivial from a scientific standpoint, as is the testing of such compositions for reactivity with Vac14. As such, there can be no meaningful challenge to enablement of claims 24-26. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

B. Second Paragraph

Claims 18, 19 and 24-26 stand rejected under the second paragraph of §112 as detailed below:

- Claim 18 is objected to for the recitation of “*Vac14 Human AA*.” This recitation has been removed from the claim, thereby obviating the rejection.
- Claim 19 is rejected for use of the phrase “non-human Vac14 sequences.” Applicants traverse, but in the interest of advancing the prosecution, the claim has been amended to remove “human” from this recitation. Thus, any sequence other than a Vac14 sequence may be fused to SEQ ID NO:3

- Claim 24 is rejected for recitation on non-elected subject matter. Applicants have amended the claim to cancel the non-elected subject matter.

Reconsideration and withdrawal of the rejections is therefore respectfully requested.

IV. Rejections Under 35 U.S.C. §102

Claims 24-26 stand rejected as anticipated by several references allegedly disclosing oligopeptides of 30 or less residues with identities ranging up to 7 residues. Applicants have amended the claims to recite a minimum size, and consecutive residues from SEQ ID NO:3, of 10 residues (see page 19, line 13 for support). Thus, the rejections are believed to be overcome, and their withdrawal is respectfully requested.

V. Conclusion

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to that effect is earnestly solicited. The examiner is invited to contact the undersigned attorney at 512-536-3184 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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Date: March 20, 2007